Dkt. 55873-BA-PCT-US/JPW/AJM/AAB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ann Marie Schmidt, et al.

U.S. Serial No.: 10/665,867

Filed : September 19, 2003

For : Extracellular RAGE Binding Protein (EN-RAGE) and Uses Thereof

1185 Avenue of the Americas
New York, New York 10036
January 6, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following disclosures, which are listed on Form PTO-1449 (**Exhibit A**).

1. U.S. Patent No. 5,688,653, November 18, 1997 (Ulrich, et al.);

2. U.S. Patent No. 5,864,018, January 26, 1999 (Morser, et al.);

3. U.S. Patent No. 5,976,832, November 2, 1999 (Hitomi, et al.);

4. Morser et al. PCT International Application No. PCT/EP97/01832, filed April 11, 1997, published October

23 1997; Publication No. WO 97/39121, Advanced Glycation Endproduct Receptor Peptides and Uses Thereof;

5. Morser et al. PCT International Application No. PCT/EP97/01834, filed April 11, 1997, published October 23 1997; Publication No. WO 97/39125, Antibodies Against the Advanced Glycation Endproduct Receptor and Uses Thereof;

6. Baynes, J. W. (1991). Role of oxidative stress in development of complications in diabetes. Diabetes 40:405-412;

7. Borchelt, D. R., et al. (1996). Familial Alzheimer's Disease-linked presenilin 1 variants elevate Aβ1-42/1-40 ratio *in vitro* and *in vivo*. Neuron 17: 1005-1013;

8. Brett, J., et al. (1993). Survey of the distribution of a newly characterized receptor for advanced glycation end products in tissues. Am. J. Pathol. 143(6):1699-1712;

9. Brownlee, M. (1992). Glycation products and the pathogenesis of diabetic complications. Diabetes Care 15(12):1835-1842;

10. Cai, X-D., et al. (1993). Release of excess amyloid β protein from a mutant amyloid β protein precursor. Science 259: 514-516;

11. Citron, M., et al. (1997). Mutant presenilins of Alzheimer's Disease increase production of 42-residue amyloid β-protein in both transfected cells and transgenic mice. Nature Medicine 3(1): 67-72;

12. Dell'Angelica, E.C., et al. (1994). Primary structure and binding properties of calgranulin C, a novel S100-like calcium-binding protein from pig granulocytes. J. Biol. Chem. 269: 28929-28936;

13. Fahey, T., et al. (1991). Diabetes impairs the late inflammatory response to wound healing. J. Surg. Res. 50: 308-313;

14. Fu, M-X., et al. (1996). The advanced glycation end product, N^{ε}-(carboxymethyl)lysine, is a product of both lipid peroxidation and glycoxidation reactions. J. Biol. Chem. 271: 9982-9986;

15. Giardino, I., et al. (1994). Nonenzymatic glycosylation *in vitro* and in bovine endothelial cells alters basic fibroblast growth factor activity. J. Clin. Invest. 94: 110-117;

16. Gibbons, G. H. and V. J. Dzau. (1996). Molecular therapies for vascular diseases. Science 272: 689-693;

17. Hofmann, M. A., et al. (1999). RAGE mediates a novel proinflammatory axis: a central cell surface receptor for s100/calgranulin polypeptides. Cell 97:889-901 **(Exhibit 1)**;

18. Hori, O., et al. (1995). The Receptor for Advanced Glycation End Products (RAGE) Is a Cellular Binding Site for Amphoterin J. Biol. Chem. 270: 25752-25761;

19. Khoury, J. E., et al., (1994). Macrophages adhere to glucose-modified basement membrane collagen IV via their scavenger receptors. J. Biol. Chem. 269: 10197-10200;

20. Kuo, Y-M., et al. (1996). Water-soluble Aβ (N-40, N-42) oligomers in normal and Alzheimer Disease brains. J. Biol. Chem. 271(8): 4077-4081;

21. Lander, H. M., et al. (1997). Activation of the receptor for advanced glycation end products triggers a $p21^{ras}$ dependent mitogen-activated protein kinase pathway regulated by oxidant stress. J. Biol. Chem. 272: 17810-17814;

22. Ledesma, M. D., et al. (1994). Analysis of microtubule-associated protein tau glycation in paired helical filaments. J. Biol. Chem. 269(34):21614-21619;

23. Li, J. and A.M. Schmidt (1997). Characterization and functional analysis of the promoter of RAGE, the receptor for advanced glycation end products. J. Biol. Chem. 272: 16498-16506;

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26. Miyata, T., et al. (1996). The receptor for advanced glycation end products (RAGE) is a central mediator of the interaction of AGE-β2 Microglobulin with human mononuclear phagocytes via an oxidant-sensitive pathway. J. Clin. Invest. 98: 1088-1094;

27. Nakamura, Y., et al. (1993). Immunohistochemical localization of advanced glycosylation endproducts in coronary atheroma and cardiac tissue in diabetes mellitus. Am. J. Pathol. 143(6): 1649-1656;

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31. Park, L., et al. (1997). A murine model of accelerated diabetic atherosclerosis: suppression by soluble receptor for advanced glycation endproducts. Circulation Supplement. Abstract 3079;

32. Reddy, S., et al. (1995). N^{ε}-(Carboxymethyl)lysine is a dominant advanced glycation end product (AGE) antigen in tissue proteins. Biochemistry 34: 10872-10878;

33. Renard, C., et al. (1997). Recombinant advanced glycation end product receptor pharmacokinetics in normal and diabetic rats. Mol. Pharm. 52: 54-62;

34. Ritthaler, U., et al. (1995). Expression of receptors for advanced glycation end products in peripheral occlusive vascular disease, Am. J. Pathol. 146: 688-694;

35. Roher, A. E., et al. (1996). Morphology and toxicity of Aβ-(1-42) dimer derived from neuritic and vascular amyloid deposits of Alzheimer's Disease. J. Biol. Chem. 271(34): 20631-20635;

36. Schleicher, E. D., et al. (1997). Increased accumulation of the glycoxidation product N^{ε}-(carboxymethyl)lysine in human tissues in diabetes and aging. J. Clin. Invest. 99: 457-468;

37. Schmidt, A. M., et al. (1995). Advanced glycation endproducts interacting with their endothelial receptor induce expression of vascular cell adhesion molecule-1 (VCAM-1) in cultured human endothelial cells and in mice. J. Clin. Invest. 96: 1395-1403;

38. Schmidt, A. M., et al. (1994). Receptor for advanced glycation endproducts (AGEs) has a central role in vessel wall interactions and gene activation in response to circulating AGE proteins. Proc. Nat'l Acad. Sci. USA 91: 8807-8811;

39. Schmidt, A. M., et al. (1992). Isolation and characterization of two binding proteins for advanced

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40. Schmidt, A. M., et al. (1994). Cellular receptors for advanced glycation end products. Arterioscler. Thromb. 14:1521-1528;

41. Schmidt, A. M., et al. (1995). The dark side of glucose. (News and Views). Nature Medicine 1: 1002-1004;

42. Schmidt, A. M., et al. (1993). Regulation of human mononuclear phagocyte migration by cell surface-binding proteins for advanced glycation end products. J. Clin. Invest. 92: 2155-2168;

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44. Schmidt, A. M., et al. (1994). The endothelial cell binding site for advanced glycation end products consists of a complex: an integral membrane protein and a lactoferrin-like polypeptide. J. Biol. Chem. 269: 9882-9888;

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implication of pentoses in the aging process. J. Biol. Chem. 264:21597-21602;

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51. Vlassara, H., et al. (1994). Pathogenic effects of advanced glycosylation: biochemical, biologic, and clinical implications for diabetes and aging. Lab. Invest. 70: 138-151;

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53. Wautier, J.-L., et al. (1996). Receptor-mediated endothelial cell dysfunction in diabetic vasculopathy:

soluble receptor for advanced glycation end products blocks hyperpermeability in diabetic rats. J. Clin. Invest. 97: 238-243;

54. Wautier, J.-L., et al. (1996). Interaction of diabetic erythrocytes bearing advanced glycation endproducts with the endothelial receptor AGE induces generation of reactive oxygen intermediates and cellular dysfunction. Circulation Supplement 94(8): #4139;

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56. Yan, S. D., et al. (1994). Enhanced cellular oxidant stress by the interaction of advanced glycation end products with their receptors/binding proteins. J. Biol. Chem. 269: 9889-9897;

57. Yan, S. D., et al. (1996). RAGE and amyloid-β peptide neurotoxicity in Alzheimer's disease. Nature 382: 685-691;

58. Yan, S. D., et al. (1997). Amyloid-β peptide-receptor for advanced glycation endproduct interaction elicits neuronal expression of macrophage-colony stimulating factor: a proinflammatory pathway in Alzheimer disease. Proc. Nat'l Acad. Sci. 94: 5296-5301.

The subject application is a continuation of and claims the benefit under 35 U.S.C. §120 of U.S. Serial No. 09/826,589, filed April 5, 2001, which is a continuation of PCT

International Application No. PCT/US99/23303, filed October 6, 1999, designating the United States of America, which is a continuation-in-part and claims priority of U.S. Serial No. 09/263,312, filed March 5, 1999, now U.S. Patent No. 6,555,340 B1, issued April 29, 2003, which is a continuation-in-part and claims priority of U.S. Serial No. 09/167,705, filed October 6, 1998, the contents of which are incorporated by reference in their entirety into the present application.

Above-listed references 1, 6-16, 19-33, 35-44, 47-51 and 53-58 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed in connection with U.S. Serial No. 09/167,705, filed October 6, 1998. Above-listed references 2, 18 and 34 were cited by the United States Patent and Trademark Office in an Office Action dated March 24, 1998 in connection with 09/167,705, filed October 6, 1998. Above-listed references 4 and 5 were submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on June 18, 2001 in connection with U.S. Serial No. 09/167,705, filed October 6, 1998. Above-listed reference 3 was cited by the United States Patent and Trademark Office in an Office Action dated December 19, 2000 in connection with 09/263,312, filed March 5, 1999, now U.S. Patent No. 6,555,340 B1, issued April 29, 2003. Above-listed references 45, 46 and 52 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed in connection with U.S. Serial No. 09/826,589, filed April 5, 2001. Accordingly, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and

Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier effective filing date under 35 U.S.C. §120. A copy of above-listed reference 17 is submitted herewith, as Exhibit 1.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

1/6/09

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Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 575-55873-BA-PCT-US/JPW/AJM/AAB	Serial No. 10/665,867
	Applicant(s) Ann Marie Schmidt, et al.	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date September 19, 2003	Group Art Unit

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		5,688,653	11/18/97	Ulrich, et al.			
		5,864,018	1/26/99	Morser, et al.			
		5,976,832	11/2/99	Hitomi, et al.			

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		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	WO	9731291	10/23/97	PCT				
	WO	9731255	10/23/97	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Baynes, J. W. (1991). Role of oxidative stress in development of complications in diabetes. Diabetes 40:405-412;
		Borchelt, D. R., et al. (1996). Familial Alzheimer's Disease-linked presenilin 1 variants elevate Aβ1-42/1-40 ratio *in vitro* and *in vivo*. Neuron 17: 1005-1013;
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		Dell'Angelica, E.C., et al. (1994). Primary structure and binding properties of calgranulin C, a novel S100-like calcium-binding protein from pig granulocytes. J. Biol. Chem. 269: 28929-28936;
		Fahey, T., et al. (1991). Diabetes impairs the late inflammatory response to wound healing. J. Surg. Res. 50: 308-313;
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		Hori, O., et al. (1995). The Receptor for Advanced Glycation End Products (RAGE) Is a Cellular Binding Site for Amphoterin J. Biol. Chem. 270: 25752-25761;
		Khoury, J. E., et al., (1994). Macrophages adhere to glucose-modified basement membrane collagen IV via their scavenger receptors. J. Biol. Chem. 269: 10197-10200;
		Kuo, Y-M., et al. (1996). Water-soluble Aβ (N-40, N-42) oligomers in normal and Alzheimer Disease brains. J. Biol. Chem. 271(8): 4077-4081;
		Lander, H. M., et al. (1997). Activation of the receptor for advanced glycation end products triggers a $p21^{ras}$ dependent mitogen-activated protein kinase pathway regulated by oxidant stress. J. Biol. Chem. 272: 17810-17814;
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		Lorenzo, A. and B.A. Yanker (1994). β-amyloid neurotoxicity requires fibril formation and is inhibited by Congo red. Proc. Nat. Acad. Sci. USA 91: 12243-12247;
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		Neeper, M., et al. (1992). Cloning and expression of a cell surface receptor for advanced glycosylation end products of proteins. J. Biol. Chem. 267: 14998-15004;
		Palinski, W., et al. (1995). Immunological evidence for the presence of advanced glycosylation end products in atherosclerotic lesions of euglycemic rabbits. Arterioscl. Thromb. and Vasc. Biol. 15(5): 571-582;
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		Renard, C., et al. (1997). Recombinant advanced glycation end product receptor pharmacokinetics in normal and diabetic rats. Mol. Pharm. 52: 54-62;
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		Schmidt, A. M., et al. (1994). The endothelial cell binding site for advanced glycation end products consists of a complex: an integral membrane protein and a lactoferrin-like polypeptide. J. Biol. Chem. 269: 9882-9888;
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Form PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 575-55873-BA-PCT-US/JPW/AJM/AAB	Serial No. 10/665,867
	Applicant(s) Ann Marie Schmidt, et al.	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date September 19, 2003	Group Art Unit

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